

Please type a plus sign (+) inside this box →



PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Application Number	09/875,349
		Filing Date	June 5, 2001
		First Named Inventor	HISERODT, JOHN C.
		Group Art Unit	1642
		Examiner Name	Unassigned
Sheet		of	9
		Attorney Docket Number	IRVN-001DIV

RECEIVED

FEB 11 2002

TECH CENTER 1600 2900

U.S. PATENT DOCUMENTS						
Examiner Initials ¹	Cite No. ¹	U.S. Patent Documents		Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, columns, lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
CY		5,290,551		Berd	03-01-1994	
		5,382,427		Plunkett et al.	01-17-1995	
		5,484,596		Hanna Jr. et al.	01-16-1996	
		5,866,115		Kanz et al.	02-02-1999	
		5,891,432		Hoo	04-06-1999	
		5,681,562		Sobol et al.	10-28-1997	
		5,109,113		Caras et al.	04-28-1992	
		4,847,201		Kawasaki et al.	07-11-1999	
		5,759,535		Cohen et al.	06-02-1998	
		5,637,483		Dranoff et al.	06-10-1997	
		5,866,115		Kanz et al.	02-02-1998	
		5,399,346		Anderson et al.	03-21-1995	
		6,051,218		McBride	04-18-2000	
CY		6,277,368 B1		Hiserodt et al.	08-21-2001	

FOREIGN PATENT DOCUMENTS							
Examiner Initials ¹	Cite No. ¹	Foreign Patent Documents			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Office ³	Number ⁴	Kind Code ⁵ (if known)			
CY			DE 441425		Germany	10-19-1995	
			EP 538952		EPO	04-28-1993	
			EP 569678		EPO	11-18-1993	
			WO 92/05805		PCT	04-16-1992	
			WO 95/16775		PCT	06-22-1995	
			WO 95/31107		PCT	11-23-1995	
			WO 96/05866		PCT	02-29-1996	
			WO 96/07433		PCT	03-14-1996	
			WO 96/29394		PCT	09-26-1996	
			WO 95/23216		PCT	08-31-1995	
			WO 97/20938		PCT	06-21-1997	
			WO 98/48012		PCT	10-29-1998	
			WO 99/06544		PCT	02-11-1999	
			WO 97/28251		PCT	08-07-1997	
			WO 93/07906		PCT	04-23-1993	
CY			WO 98/06746		PCT	02-19-1998	

Please type a plus sign (+) inside this box →



PTO/SB/08A (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO		Complete if Known		RECEIVED
		Application Number	09/875,349	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Filing Date	June 5, 2001	FEB 11 2002
		First Named Inventor	HISERODT, JOHN C.	
		Group Art Unit	1642	
		Examiner Name	Unassigned	
		Attorney Docket Number	IRVN-001DIV	
(use as many sheets as necessary)				
Sheet	3	of	9	TECH CENTER 1600/2900

OTHER PRIOR ART—NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
CY		Abe et al., "Cytokine-gene-modified tumor vaccination intensified by a streptococcal preparation OK-432" <u>Cancer Immunol. Immunother.</u> (1995) 41:82-86.	
CY		Allione et al. "Immunizing and curative potential of replicating and nonreplacing murine mammary adenocarcinoma cells engineered with interleukin (IL-)2, IL-4, IL-6, IL-7, IL-10, tumor necrosis factor, granulocyte-macrophage colony-stimulating factor, and -interferon gene or admixed with conventional adjuvants" <u>Cancer Res.</u> (1994) 54:6022-6026.	
CY		Asher et al. "Murine tumor cells transduced with the gene for tumor necrosis factor- " <u>J. Immunology.</u> (1991) 146:3227-3234.	
CY		Berd et al. "Treatment of metastatic melanoma with an autologous tumor-cell vaccine: Clinical and immunologic results in 64 patents" <u>J. Clin. Oncol.</u> (1990) 8:1858-1867.	
CY		Blankenstein et al. "Tumor suppression after tumor cell-targeted necrosis factor gene transfer" <u>J. Exp. Med.</u> (1991) 173:1047-1052.	
CY		Borden, Ernst C. and Sondel, Paul M., "Lymphokines and Cytokines as Cancer". 65:800-814, (1990).	
CY		Borrelli, Emiliana, et al. "Targeting of an Inducible Toxic Phenotype in Animal Cells." <u>Proc. Natl. Acad. Sci USA.</u> 85:7572-7576 (1988).	
CY		Brown, D. "Gene Therapy 'Oversold' by Researchers, Journalists," <u>The Washington Post</u> , A22, Dec.8, 1995.	
CY		Bubenik, J. et al., "Immunotherapy of Cancer using Local Administration of Lymphoid Cells Transformed by IL-2c DNA and Constitutively Producing IL-2". <u>Immunology Letters</u> 23:287-292 (1998/1990).	
CY		Bubenik, J. et al., "Local Administration of Cells Containing an Inserted IL-2 Gene and Producing U2 Inhibits Growth of Human Tumors in Nu/Nu Mice." <u>Immunology Letters.</u> 19:279-282 (1988).	
CY		Coghlan, A. "Gene dream fades away," <u>New Scientist</u> , vol. 145:14-15, Nov. 25, 1995.	
CY		Colombo, "Tumor cells engineered to produce cytokines or cofactors as cellular vaccines: do animal studies really support clinical trials?" <u>Cancer Immunol. Immunother.</u> (1995) 41:265-270.	
CY		Colombo, et al. "Granulocyte Colony-stimulating a Factor Gene Transfer Suppresses Tumorigenicity of a Murine Adenocarcinoma in Vivo." <u>J. Exp. Med.</u> 173:889-897 (1991).	
CY		Dillman et al., "Establishing <i>in vitro</i> cultures of autologous tumor cells for use in active specific immunotherapy" <u>J. Immunother.</u> (1993) 14:65-69.	
CY		Dranoff et al., "Vaccination with irradiated tumor cells engineered to secrete murine granulocytemacrophage colony-stimulating factor stimulates potent, specific, and long lasting anti-tumor immunity" <u>Proc. Natl. Acad. Sci. USA</u> (1993) 90:3539-3543.	
CY		Fakhrai et al., "Cytokine gene therapy with interleukin-2 transduced fibroblasts: effects of IL-2 dose on anti-tumor immunity" <u>Human Gene Therapy</u> (1995) 6:591-601.	

RECEIVED

FEB 11 2002

Please type a plus sign (+) inside this box →



TECH CENTER 1600/2900

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0851-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	09/875,349
		Filing Date	June 5, 2001
		First Named Inventor	HISERODT, JOHN C.
		Group Art Unit	1642
		Examiner Name	Unassigned
		Attorney Docket Number	IRVN-001DIV
Sheet	4	of	9

CY	Fearon et al., "Interleukin-2 production by tumor cells bypasses T helper function in the generation of an antitumor response" <i>Cell</i> (1990) 60:397-403.	
CY	Gabrilove, Janice 1. and Jakubowski, Ann "Hematopoietic Growth Factors: Biology and Clinical Application". <i>J of the National Cancer Inst. Monographs</i> . 10:73-77 (1990).	
CY	Gandolfi, L. et al., "Intratatumoral Echo-guided Injection of Interleukin-2 and Lymphokine Activated Killer Cells in Hepatorcellular Carcinom." <i>Hepato-gastroenterol</i> 36:352-356 (1989).	
CY	Gansbacher Bernd, et al., "Retroviral Vector-Mediated. Tau. Interferon Gene Transfer into Tumor Cells Generates Potent and Antitumor Immunity." <i>Cancer Research</i> 50:7820-7825 (1990).	
CY	Gansbacher, Bernd et al., "Interleukin 2 Gene Transfer into Tumor Cells Abrogates Tumorigenicity and Induces Protective Immunity", <i>J. Exp. Med</i> , 90:1237-1224 (1990).	
CY	Gansbacher, et al. "Retroviral Vector-Mediated Cytokine-Gene Transfer into Tumor Cells." <i>Cancer Investigation</i> , vol. 11(3):345-354, Mar. 1993.	
CY	Golumbek et al., "Controlled release, biodegradable cytokine depots: a new approach in cancer vaccine design" <i>Cancer Research</i> (1993) 53:5841-5844.	
CY	Golumbek et al., "Herpes simplex-1 virus thymidine kinase gene is unable to completely eliminate live, nonimmunogenic tumor cell vaccines" <i>J. Immunother.</i> (1992) 12:224-230.	
CY	Golumbek et al., "Treatment of established renal cancer by tumor cells engineered to secrete interleukin-4" <i>Science</i> (1991) 254:713-716.	
CY	Graf et al. Development of systemic immunity to glioblastoma multiforme using tumor cells genetically engineered to express the membrane-associated isoform of macrophage colony-stimulating factor. <i>J. Immunol.</i> 163:5544, 1999.	
CY	Graf et al., "Adenovirus-mediated gene transfer into experimental rat gliomas" <i>Soc. Neuroscience</i> (1995) 21:2135 (Abstract 838.5)	
CY	Graf et al., "T9 rat glioma cells secreting human TNF immunize Fischer rats against untransfected T9 and L9 gliomas" <i>Proc. Amer. Assoc. Cancer Res.</i> (1994) 35:500 (Abstract 2978).	
CY	Hoover, H.C. Jr. et al., "Delayed Cutaneous Hypersensitivity to Autologous Tumor Cells in Colorectal Cancer Patients Immunized With the Autologous Tumor Cell": <i>Bacillus-calmette Guerin Vaccine</i> , <i>Cancer Res.</i> 44:1671-1676 (1984).	
CY	Jadus et al. Macrophages can recognize and kill tumor cells bearing the membrane isoform of macrophage colony stimulating factor. <i>Blood</i> 87:5232, 1996.	
CY	Jaffee et al. Considerations for the clinical development of cytokine gene-transduced tumor cell vaccines. <i>Methods</i> 12:143, 1997.	
CY	Karp et al. In vivo activity of tumor necrosis factor (TNF) mutants. Secretory but not membrane-bound TNF mediates the regression of retrovirally transduced murine tumor. <i>J. Immunol.</i> 149:2076, 1992.	
CY	Karp et al., "Cytokine secretion by genetically modified nonimmunogenic murine fibrosarcoma" <i>J. Immunol.</i> (1993) 150:896-908.	

FEB 11 2002

Please type a plus sign (+) inside this box →



TECH CENTER 1600/2900

PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	09/875,349
		Filing Date	June 5, 2001
		First Named Inventor	HISERODT, JOHN C.
		Group Art Unit	1642
		Examiner Name	Unassigned
		Attorney Docket Number	IRVN-001DIV
Sheet	5	of	9

cy	Kondo et al., "Rationale for a novel immunotherapy of cancer with allogeneic lymphocyte infusion" <i>Med. Hypotheses</i> (1984) 15:241-277.
	Kriegler et al. A novel form of TNF/cachectin is a cell surface cytotoxic transmembrane protein: ramifications for the complex physiology of TNF. <i>Cell</i> 53:45, 1988.
	Kruse et al., "Analysis of interleukin 2 and various effector cell populations in adoptive immunotherapy of 9L rat gliosarcoma: Allogeneic cytotoxic T lymphocytes prevent tumor take" <i>Proc. Natl. Acad. Sci. USA</i> (1990) 87:9577-9581.
	Kruse et al., "Intracranial administrations of single or multiple source allogeneic cytotoxic T lymphocytes: chronic therapy for primary brain tumors" <i>J. Neuro-Oncol.</i> (1994) 19:161-168.
	Kruse et al., "Systemic chemotherapy combined with local adoptive immunotherapy cures rats bearing 9L gliosarcoma" <i>J. Neurooncol</i> (1993) 15:97-112.
	Lange, et al., "A Pilot Study of the Combination of Interleukin-2- Bases Immunotherapy and Radiation Therapy." <i>Journal of Immunology</i> 12:265-271 (1992).
	Lesham et al. <i>Cancer Immunol. Immunotherap.</i> (1984) Vol. 17:117-123.
	Li Xu, et al, "Factors Affecting Long-Term Stability of Moloney Murine Leukemia Virus-Based Vectors". <i>Virology</i> 171:331-341 (1989).
	Lotze et al., "Gene therapy of cancer: a pilot study of IL-4-gene-modified fibroblasts admixed with autologous tumor to elicit an immune response" <i>Human Gene Therapy</i> (1994) 5:41-55.
	Lotze, Michael T. and Finn, Olivera J., "Recent Advances in Cellular Immunology: Implication for Immunity to Cancer." <i>Immunotherapy Today</i> 11:190-193 (1990).
	Lotze, Michael T. et al., "Mechanisms of Immunologic Antitumor Therapy: Lesson from the Laboratory and Clinical Applications." <i>Fundamental Immunology</i> , Second Edition. 923-942 (1989).
	Lotze, Michael T. et al., "High-Dose Recombinant Interleukin 2 in the Treatment of Patients with Disseminated Cancer." <i>JAMA</i> 256:3117-3124 (1986).
	Mackensen et al., "Immunostimulatory cytokines in somatic cells and gene therapy of cancer" <i>Cytokine & Growth Factor Reviews</i> (1997) 8:119-128.
	Mackensen et al., "Induction of tumor-specific cytotoxic T lymphocytes by immunization with autologous tumor cells and interleukin-2 gene transfected fibroblasts" <i>J. Mol. Med</i> (1997) 75:290-296.
	Malcolm S Mitchell, "Combining Chemotherapy and Biomodulation in the Treatment of Cancer, in Human Tumor Antigens and Specific Tumor Therapy, UCLA Symposium at Keystone Colorado 91345-358 (Metzgar and Mitchell ed., 1989).
	Matsumoto et al., "Recombinant Human Granulocyte Colony-Stimulating Factor Inhibits the Metastasis of Hematogenous and Non-Hematogenous Tumors in Mice." <i>Int. J. Cancer</i> 49:444-449(1991).
cy	McBride and Dougherty, "Radiotherapy for genes that cause cancer" <i>Nature Medicine</i> 1:1215-1217 (1995).

RECEIVED

FEB 11 2002

TECH CENTER 1600/2900

Please type a plus sign (+) inside this box →



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	09/875,349
		Filing Date	June 5, 2001
		First Named Inventor	HISERODT, JOHN C.
		Group Art Unit	1642
		Examiner Name	Unassigned
		Attorney Docket Number	IRVN-001DIV
Sheet	6	of	9

eY	McBride et al. "Interleukin-3 in Gene Therapy of Cancer," <i>Folia Biologica</i> , vol. 40:62-73, Feb. 1994.
	McBride et al., "Modification of Tumor Microenvironment by Cytokine Gene Transfer." <i>Acta Oncologica</i> 34:447-451 (1995)
	McDonald et al., "Combined Betaseron R (Recombinant Human Interferon Beta) and Radiation for Inoperable Non-Small Cell Lung Cancer." <i>Int. J. Radiation Oncology Biol. Phys.</i> 27:613-619, 1993.
	Mertelsmann et al., "Pilot study for the evaluation of T-cell mediated tumor immunotherapy by cytokine gene transfer in patients with malignant tumors" <i>J. Mol Med</i> (1995) 73:205-206.
	Mitchell et al, "Active specific immunotherapy of melanoma with allogeneic cell lysates. Rationale, results, and possible mechanisms of action" <i>Ann. N.Y. Acad. Sci.</i> (1993) 690:153-166.
	Mitchell, et al., "Combining Chemotherapy and Biomodulation in the Treatment of Cancer," Human Tumor Antigens and Specific Tumor Therapy, UCLA Symposium at Keystone Colorado. Ed., Metzgar, et al., New York: Alan R. Liss, Inc., 1989, Vol. 99, pages 345-358.
	Ogura, Hiromi et al., Implantation of Genetically Manipulated Fibroblasts into Mice as Antitumor. Alpha-Interferon Therapy." <i>Cancer Research</i> 50:5101-5106 (1990).
	Patchen et al., "Mast cell growth factor (C-kit ligand) in combination with granulocyte-macrophage colony-stimulating factor and interleukin-3: <i>in vivo</i> hemopoietic effects in irradiated mice compared to <i>in vitro</i> effects," <i>Biotherapy</i> , vol. 7:13-26, July 1994.
	Peace, David J et al., "T Cell Recognition of Transforming Proteins Encoded by Mutated ras Proto-Oncogenes." <i>J. Immunology.</i> 146:2059-2065 (1991).
	Perez et al. A nonsecretable cell surface mutant of tumor necrosis factor (TNF) kills by cell to cell contact. <i>Cell</i> 63:251, 1990.
	Pizza, G. et al., "Intra-Lymphatic Administration of Interleukin-2 (IL-2) in Cancer Patients: A Pilot Study." <i>Lymphokine Research</i> 7:45-48 (1988).
	Plaksin et al., "Effective anti-metastatic melanoma vaccination with tumor cells transfected with MHC genes and/or infected with newcastle disease virus (NDV)" <i>Int. J. Cancer</i> (1994) 59:796-801.
	PRESS RELEASE, Immune Response Corporation, February 22, 2000. The Immune Response Corporation announces preclinical results for a genetically engineered cancer vaccine.
	PRESS RELEASE, Immune Response Corporation, October 11, 1999. The Immune Response Corporation reports investigational colon cancer vaccine Phase I trial data in <i>Clinical Cancer Research</i> .
↓	Redd et al., "Allogeneic tumor-specific cytotoxic T lymphocytes" <i>Cancer Immunol. Immunother.</i> (1992) 34:349-354.
CY	Rosenberg, Steven A. "The Immunotherapy and Gene Therapy of Cancer." <i>J. Clin. Oncology</i> 10:180-199 (1992).

RECEIVED

FEB 11 2002

TECH CENTER 1600/2900

Please type a plus sign (+) inside this box →



Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	09/875,349
		Filing Date	June 5, 2001
		First Named Inventor	HISERODT, JOHN C.
		Group Art Unit	1642
		Examiner Name	Unassigned
		Attorney Docket Number	IRVN-001DIV
Sheet	9	of	9

cy		Zarling et al., "Generation of cytotoxic T lymphocytes to autologous human leukemia cells by sensitization to pooled allogeneic normal cells" <i>Nature</i> (1978) 274: 269-271.	
I		Zatloukalet al., "Elicitation of a systemic and protective anti-melanoma immune response by an IL-2-based vaccine" <i>The Journal of Immunology</i> (1995) 154:3406-3419.	
↓		Zhang et al. "Gene Therapy strategies for cancer," <i>Expert Opinion on Investigational Drugs</i> , Vol. 4 (6):487-514, Jun. 1995.	

Examiner Signature	Christopher H Yea	Date Considered	9-30-02
-----------------------	-------------------	--------------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box →



PTO/SB/08A (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known		RECEIVED FEB 11 2002 TECH CENTER 1600/2900	
		Application Number	09/875,349		
		Filing Date	June 5, 2001		
		First Named Inventor	HISERODT, JOHN C.		
		Group Art Unit	1642		
		Examiner Name	Unassigned		
Sheet	2	of	9	Attorney Docket Number	IRVN-001DIV

CY		WO 98/16246	PCT	04-23-1998	
		WO 95/23216	PCT	08-31-1995	
		WO 98/48012	PCT	10-29-1998	
		WO 97/20938	PCT	06-12-1997	
		WO 92/05262	PCT	02-1992	
CY					

Examiner Signature	<i>Christopher H. Y...</i>	Date Considered	9-30-02
--------------------	----------------------------	-----------------	---------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard St.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.